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PTO-1449)

ATTY. DOCKET NO.  
CI-0004APPLN. SERIAL NO.  
09/942,938APPLICANT  
David M. MANNFILING DATE  
August 31, 2001GROUP  
1614

## U.S. PATENT DOCUMENTS

EXAMINER'S INITIALS	*PATENT NO.	*ISSUE DATE	*INVENTOR NAME	CLASS	SUBCLASS	FILING DATE
W	RE 23,195	02/1950	Arno Brasch			
W	2,832,689	04/1958	Bernard E. Proctor et al.			
W	2,920,969	01/1960	E.S. Stoddard			
W	2,962,380	11/1960	J.H. Wertheim			
W	3,620,944	11/1971	Keiko Tanito			
W	3,743,480	07/1973	John D. Falk			
W	3,779,706	12/1973	Nablo			
W	4,136,094	01/1979	Condie			
W	4,251,437	02/1981	Rasmussen et al.			
W	4,282,863	08/1981	Beigler et al.			
W	4,330,626	05/1982	Blair et al.			

## U.S. PATENT APPLICATION PUBLICATIONS

	*PATENT APPLN. PUB. NO.	*PUB. DATE	*APPLICANT	CLASS	SUBCLASS	

## U.S. PATENT APPLICATIONS

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## FOREIGN PATENT DOCUMENTS

EXAMINER'S INITIALS	PATENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	Translation	
						Yes	No
W	2,056,619	10/1991	Canada			X	
W	310 316	04/1989	Europe (Abstract)			X	
W	334 679	09/1989	Europe (Abstract)			X	
W	919 918 A2	06/1999	Europe (Abstract)			X	
W	919 918 A3	06/1999	Europe (Abstract)			X	

## OTHER ART (Including Author, Title, Date, Pertinent Pages, Publisher, Place of Publication, Etc.)

W	AABB FDA Liaison Meeting, ABC Newsletter, December 12, 1997, pp. 14				
W	Ozan Akkus et al., Fracture Resistance of Gamma Radiation Sterilized Cortical Bone Allografts, 2001, pps. 927-934, Journal of Orthopaedic Research, Vol. 19				
W	Tikvah Alper et al., The Exceptionally Small Size of the Scrapie Agent, 1966, pps. 278-284, Biochemical and Biophysical Research Communications, Vol. 22, No. 3				

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5/5/03

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# LIST OF PRIOR ART CITED BY APPLICANT

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(PTO-1449)

ATTY. DOCKET NO.  
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APPLN. SERIAL NO.  
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APPLICANT  
**David M. MANN et al.**

FILING DATE  
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## U.S. PATENT DOCUMENTS

EXAMINER'S INITIALS	*PATENT NO.	*ISSUE DATE	*INVENTOR NAME	CLASS	SUBCLASS	FILING DATE
<i>N</i>	4,370,264	01/1983	Kotitschke et al.			
<i>N</i>	4,409,105	10/1983	Hayashi et al.			
<i>N</i>	4,472,840	09/1984	Jefferies			
<i>N</i>	4,620,908	11/1986	Van Duzer			
<i>N</i>	4,865,602	09/1989	Smestad et al.			
<i>N</i>	4,933,145	06/1990	Uchida et al.			
<i>N</i>	4,946,648	08/1990	Dichtelmüller et al.			
<i>N</i>	4,963,356	10/1990	Calenoff et al.			
<i>N</i>	5,000,951	03/1991	Bass et al.			
<i>N</i>	5,106,619	04/1992	Wiesehahn et al.			
<i>N</i>	5,134,295	07/1992	Wälschmiller			
<i>N</i>	5,185,371	02/1993	Rubinstein			

## U.S. PATENT APPLICATION PUBLICATIONS

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						Yes	No
<i>N</i>	11-216147	08/1999	Japan (Abstract)			X	
<i>N</i>	1321420-A	07/1987	Soviet Union (Abstract)			X	
<i>N</i>	WO 90/00907	02/1990	PCT Int'l (Abstract)			X	
<i>N</i>	WO 91/16060	10/1991	PCT Int'l (Abstract)			X	
<i>N</i>	WO 95/03071	02/1995	PCT Int'l (Abstract)			X	

## OTHER ART (Including Author, Title, Date, Pertinent Pages, Publisher, Place of Publication, Etc.)

<i>N</i>	Tikvah Alper et al., Protection by Anoxia of the Scrapie Agent and Some DNA and RNA Viruses Irradiated as Dry Preparations, 1968, pps. 157-166, J. Gen. Virol., Vol. 3
<i>N</i>	Tikvah Alper et al., Does the Agent of Scrapie Replicate Without Nucleic Acid? May 20, 1967, pps. 764-766, Nature, Vol. 214
<i>N</i>	Tikvah Alper et al., The Scrapie Agent: Evidence Against its Dependence For Replication on Intrinsic Nucleic Acid, 1978, pps. 503-516, J. Gen. Virol., Vol. 41
EXAMINER	DATE CONSIDERED <i>5/5/2003</i>

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EXAMINER'S INITIALS	*PATENT NO.	*ISSUE DATE	*INVENTOR NAME	CLASS	SUBCLASS		
<i>W</i>	5,226,065	07/1993	Held et al.				
<i>W</i>	5,362,442	11/1994	Kent				
<i>W</i>	5,418,130	05/1995	Plat. et al.				
<i>W</i>	5,460,962	10/1995	Kemp				
<i>W</i>	5,510,122	04/1996	Sreebny et al.				
<i>W</i>	5,603,894	02/1997	Aikus et al.				
<i>W</i>	5,609,864	03/1997	Shanbrom				
<i>W</i>	5,637,451	06/1997	Ben-Hur et al.				
<i>W</i>	5,643,464	07/1997	Rhee et al.				
<i>W</i>	5,712,086	01/1998	Horowitz et al.				
<i>W</i>	5,730,933	03/1998	Peterson				
<i>W</i>	5,817,528	10/1998	Böhm et al.				
<b>U.S. PATENT APPLICATION PUBLICATIONS</b>							
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<b>FOREIGN PATENT DOCUMENTS</b>							
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<i>W</i>	WO 00/25839	03/2000	PCT Int'l (Abstract)			X	
<i>W</i>	WO 01/08611A1	02/2001	PCT Int'l (Abstract)			X	
<i>W</i>	WO 01/12318A1	02/2001	PCT Int'l (Abstract)			X	
<i>W</i>	WO 01/32107A2	05/2001	PCT Int'l (Abstract)			X	
<i>W</i>	WO 01/32110A2	05/2001	PCT Int'l (Abstract)			X	
<b>OTHER ART (Including Author, Title, Date, Pertinent Pages, Publisher, Place of Publication, Etc.)</b>							
<i>W</i>	S.R. Aparicio et al., Light and Electron Microscopy Studies on Homograft and Heterograft Heart Valves, 1975, pps. 174-162, J. Path, Vol. 115						
<i>W</i>	J. Baksa et al., The Use of Pig's Skin (xenograft) for the Treatment of Burns, 1976, pps. 138-145, Magyar Traumatologin, Vol. 19						
<i>W</i>	Michael L. Baldwin et al., Irradiation of Blood Components, 1992, pps. 10-78, American Association of Blood Banks						
EXAMINER	<i>W</i>			DATE CONSIDERED		5/5/2003	

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EXAMINER'S INITIALS	*PATENT NO.	*ISSUE DATE	*INVENTOR NAME	CLASS	SUBCLASS	FILING DATE
W	5,837,313	11/1998	Ding et al.			
W	5,881,534	03/1999	Ahlqvist et al.			
W	5,981,163	11/1999	Horowitz et al.			
W	5,986,168	11/1999	Noishiki			
W	6,046,024	04/2000	Burton et al.			
W	6,049,025	04/2000	Stone et al.			
W	6,066,626	05/2000	Yew et al.			
W	6,087,141	07/2000	Margolis-Nunno et al.			
W	6,120,592	09/2000	Brault et al.			
W	6,159,490	12/2000	Deghenghi			
W	6,171,549	01/2001	Kent			

## U.S. PATENT APPLICATION PUBLICATIONS

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EXAMINER'S INITIALS	PATENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	Translation	
						Yes	No
W	WO 01/45720A1	06/2001	PCT Int'l (Abstract)			X	
W	WO 01/49219A1	07/2001	PCT Int'l (Abstract)			X	
W	WO 01/72233A1	10/2001	PCT Int'l (Abstract)			X	
W	WO 01/72244A1	10/2001	PCT Int'l (Abstract)			X	
W	WO 01/91818A1	12/2001	PCT Int'l (Abstract)			X	

## OTHER ART (Including Author, Title, Date, Pertinent Pages, Publisher, Place of Publication, Etc.)

W	R.H. Bassin et al., Abrogation of Fv-1 <sup>b</sup> Restriction With Murine Leukemia Viruses Inactivated by Heat or by Gamma Irradiation, May 1978, pps. 306-315, Journal of Virology, Vol. 26, No. 2
W	Guy Beauregard et al., Temperature Dependence of the Radiation Inactivation of Proteins, 1985, pps. 117-120, Analytical Biochemistry, Vol. 150
W	Sandra Blakeslee, Tight Rules on Use of Organs Do Not Apply to Tissues, January 20, 2002, The New York Times Newspaper

EXAMINER

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<b>LIST OF PRIOR ART CITED BY APPLICANT</b> (PTO-1449)		ATTY. DOCKET NO. <b>CI-004</b>	APPLN. SERIAL NO. <b>09/942,938</b>
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<b>OTHER ART (Including Author, Title, Date, Pertinent Pages, Publisher, Place of Publication, Etc.)</b>			
		P. Brown, The Risk of Blood-Borne Creutzfeldt-Jakob Disease, 1999, pps. 53-59, Advances in Transfusion Safety Dev. Biol. Vol. 102	
N		P. Brown et al., Further Studies of Blood Infectivity in an Experimental Model of Transmissible Spongiform Encephalopathy, With an Explanation of Why Blood Components Do Not Transmit Creutzfeldt-Jakob Disease in Humans, November/December 1999, pps. 1169-1178, Transfusion, Vol. 39	
N		Paul Brown et al., Effect of Chemicals, Heat, and Histopathologic Processing on High-Infectivity Hamster-Adapted Scrapie Virus, May 1982, pps. 683-687, The Journal of Infectious Diseases, Vol. 145, No. 5	
N		P. Brown et al., The Distribution of Infectivity in Blood Components and Plasma Derivatives in Experimental Models of Transmissible Spongiform Encephalopathy, September 1998, pps. 810-816, Transfusion, Vol. 38	
N		D.G. Campbell et al., Sterilization of HIV With Irradiation: Relevance to Infected Bone Allografts, 1999, pps. 517-521, Aust. N.Z.J. Surg., Vol. 69	
N		Ernest U. Conrad et al., Transmission of the Hepatitis-C Virus by Tissue Transplantation, February 1995, pps. 214-224, The Journal of Bone and Joint Surgery, Vol. 77-A, No. 2	
N		A.S. Dagli, Correction of Saddle Nose Deformities by Coral Implantation, 1997, pps. 274-276, Eur. Arch. Otorhinolaryngol, Vol. 254	
N		Defeng et al., Sterilization of Silver-Acidum Pipemedicum Skin for the Treatment of Burns by Radioactive Cobalt-60-Gamma-Ray, 1995, pps. 406 (Abstract)	
N		P. Di Simplicio et al., The Reactivity of the SH Group of Bovine Serum Albumin With Free Radicals, 1991, pps. 253-262, Free Rad. Res. Comms., Vol. 14, No. 4	
N		R.J. Donnelly et al., Gamma-radiation of Heart Valves at 4°C; A Comparative Study Using Techniques of Histochemistry and Electron and Light Microscopy, 1973, pps. 95-101, Thorax, Vol. 28	
N		Duane C. Eichler et al., Radiation Inactivation Analysis of Enzymes, July 15, 1987, pps. 9433-9436, The Journal of Biological Chemistry, Vol. 262, No. 20	
N		Luanne H. Elliott et al., Inactivation of Lassa, Marburg and Ebola Viruses by Gamma Irradiation, Oct. 1982, pps. 704-708, Journal of Clinical Microbiology, Vol. 16, No. 4	
N		Bradley M. Fideler et al., Gamma Irradiation: Effects on Biomechanical Properties of Human Bone-Patellar Tendon-Bone Allografts, 1995, pps. 643-646, American Journal of Sports Medicine, Vol. 23, No. 5	
N		Bradley M. Fideler et al., Effects of Gamma Irradiation on the Human Immunodeficiency Virus, July 1994, The Journal of Bone and Joint Surgery, Vol. 76-A, No. 7	
N		Fields et al., Susceptibility of Scrapie Agent to Ionizing Radiation, April 5, 1969, pps. 90-91, Nature, Vol. 222	
N		M.J. Gibbons et al., Effects of Gamma Irradiation on the Initial Mechanical and Material Properties of Goat Bone Patellar Tendon-Bone Allografts, 1991, pps. 209-218, J. Orthop Res, Vol. 9, No. 2	
EXAMINER		DATE CONSIDERED	

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<b>OTHER ART (Including Author, Title, Date, Pertinent Pages, Publisher, Place of Publication, Etc.)</b>			
	J.R.P. Gibbons et al., Gamma Ray Sterilisation of Homograft Valves, 1969, pps. 353-358, Bulletin De La		
	Societe Internationale De Chirurgie, No. 3		
N	M.J. Goertzen et al., Anterior Cruciate Ligament Reconstruction Using Cryopreserved Irradiated		
	Bone-ACL-Bone-Allograft Transplants, 1994, pps. 150-157, Knee Surgery Sports Traumatology Arthroscopy, Vol. 2		
N	M.J. Goertzen et al., Sterilisation of Canine Anterior Cruciate Allografts by Gamma Irradiation in Argon,		
	March 1995, pps. 205-212, The Journal of Bone and Joint Surgery, Vol. 77-B, No. 2		
N	Slawomir Gregorczyk et al., Strength of Lyophilized and Irradiated Cortical Bone of the Human Femur,		
	1995, pps. 129-133, Chir. Narz. Ruchu Ortop. Pol., Lx 2		
N	D.A. Haig, Further Studies on the Inactivation of the Scrapie Agent by Ultraviolet Light, 1969,		
	pps. 455-457, J. Gen. Virol., Vol. 5		
N	F.W. Hehrlein et al., Biochemische Veränderungen an Heterologen Aortenklappentransplantaten nach		
	Anwendung Verschiedener Sterilisationsverfahren, pps. 1183-1185, Langenbecks Arch. Chir., Bd. 325 (Kongrebericht)		
	(English Summary found at page 1183)		
N	F.W. Hehrlein et al., Morphologische Untersuchungen an Heterologen Herzklappentransplantaten Unter		
	Verschiedenen Sterilisationsbedingungen, pps. 244-251 (English Summary found at page 250)		
N	H. Hiemstra et al., Inactivation of Human Immunodeficiency Virus by Gamma Radiation and its Effect on		
	Plasma and Coagulation Factors, 1991, pps. 32-39, Transfusion, Vol. 31, No. 1		
N	Richard Hinton et al., A Biomechanical Analysis of Solvent-dehydrated and Freeze-Dried Human Fascia		
	Lata Allografts, 1992, pps. 607-612, The American Journal of Sports Medicine, Vol. 20, No. 5		
N	B. Horowitz et al., Inactivation of Viruses in Labile Blood Derivatives, II. Physical Methods,		
	1985, pps. 523-527, Transfusion, Vol. 25, No. 6		
N	M. Horowitz, Sterilization of Homograft Ossicles by Gamma Radiation, November 1979, pps. 1087-1089,		
	The Journal of Laryngology and Otology, Vol. 93		
N	Carol House et al., Inactivation of Viral Agents in Bovine Serum by Gamma Irradiation, 1990		
	pps. 737-740, Can. J. Microbiol., Vol. 36		
N	Shinichiro Ijiri et al., Effect of Sterilization on Bone Morphogenetic Protein, 1994, pps. 628-636,		
	Journal of Orthopaedic Research, Vol. 12		
N	A.S. Imamaliyev et al., Biological Properties of Bone Tissue Conserved in Plastic Material and Sterilized		
	With Gamma Rays, 1974, pps. 129-135, ACTA, Chirurgiae Plasticae, Vol. 16, No. 3		
N	A. Ingegneri et al., An 11-Year Assessment of 93 Flash-frozen Homograft Valves in the Aortic Position,		
	1979, pps. 304-307, Thorac. Cardiovasc. Surgeon, Vol. 27		
N	J. Jerosch et al., A New Technique for Bone Sterilization, 1989, pps. 117-120, Biomedizinische		
	Technik, Band 34, Heft 5		
N	J. Jerosch et al., Influence of Different Rehydration Periods on the Stability and the Water Content of Bone Allografts		
	After Lyophilization, Gamma-Irradiation, and Lipid Extraction, 1994, pps. 335-341, Z. Orthop., Vol. 132		
N	J.D. Keathley et al., Is There Life After Irradiation? Part 2: Gamma-Irradiated FBS in Cell Culture		
	July/August 1993, pps. 46-52, BioPharm		
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**OTHER ART INCLUDING Author, Title, Date, Pertinent Pages, Publisher, Place of Publication, etc.)**

	E.S. Kempner et al., Size Determination of Enzymes by Radiation Inactivation, 1979, pps. 2-10, Analytical Biochemistry, Vol. 92
	L. Kerboul et al., In Vitro Study of the Influence of Various Conservation Methods on the Mechanical Properties of Patellar Tendon Allografts, 1991, pps. 751-762, Chirurgie, Vol. 117
	A.D. Kitchen, Effect of Gamma Irradiation on the Human Immunodeficiency Virus and Human Coagulation Proteins, 1989, pps. 223-229, Vox Sang, Vol. 56
	Andrezej Komender et al., Some Biological Properties of Bovine Trypsinized Fascia Xenografts, 1981, pps. 485-489, Archivum Immunologiae et Therapiae Experimentalis, Vol. 29
	Andrezej Komendar et al., Some Biological Properties of Preserved Bovine Fascia Enriched With Pulverized Calf Cartilage, 1984, pps. 211-219, Archivum Immunologiae et Therapiae Experimentalis, Vol. 32
	J.F. Kouvalchouk et al., The Use of Sterilized Bone Allografts in Reconstruction After Tumour Resection, 1986, pps. 393-401, Revue de Chirurgie Orthopedique, Vol. 72
	Raymond Latarjet, Inactivation of the Agents of Scrapie, Creutzfeldt-Jakob Disease, and Kuru by Radiations, 1979, pps. 387-407, Slow Transmissible Diseases of the Nervous System, Vol. 2
	R. Latarjet et al., Inactivation of the Scrapie Agent by Near Monochromatic Ultraviolet Light, September 26, 1970, pps. 1341-1343, Nature, Vol. 227
	Douglas C. Lee et al., A Direct Relationship Between the Partitioning of the Pathogenic Prion Protein and Transmissible Spongiform Encephalopathy Infectivity During the Purification of Plasma Proteins, April 2001, pps. 449-455, Transfusion, Vol. 41
	Susan F. Leitman, Use of Blood Cell Irradiation in the Prevention of Posttransfusion Graft-vs-Host Disease, 1989, pps. 219-232, Transfus. Sci., Vol. 10
	Linberg et al., Irradiated Homologous Cartilage For Orbital Reconstruction, July 1980, pps. 457-462, Ophthalmic Surgery, Vol. 11
	Sandra McDowell, Irradiated Cartilage, Spring 1988, pps. 14-15, Plastic Surgical Nursing
	A. Maeda et al., Effects of Solvent Preservation With or Without Gamma Irradiation on the Material Properties of Canine Tendon Allografts, 1993, pps. 181-189, Journal of Orthopaedic Research, Vol. 11
	Akira Maeda et al., Solvent-dried and Gamma-irradiated Tendon Allografts in Rats, July 1998, pps. 731-736, The Journal of Bone and Joint Surgery, Vol. 80-B, No. 4
	S. Malawski et al., The Use of Dry-Freeze Bone Grafts Sterilized by Gamma Rays in Orthopaedic Surgery, 1969, pps. 61-68, Chir. Narz. Ruchu Ortop.
	Linda Marton et al., Disinfection and Inactivation of the Human T. Lymphotropic Virus Type III/Lymphadenopathy-Associated Virus, August 1985, pps. 499-503, The Journal of Infectious Diseases, Vol. 151, No. 2
	S.I. Miekka et al., New Methods for Inactivation of Lipid-enveloped and Non-enveloped Viruses, 1998, pps. 402-408, Haemophilia, Vol. 4
	Ken Nakata et al., Reconstruction of the Lateral Ligaments of the Ankle Using Solvent-dried and Gamma-Irradiated Allogeneic Fascia Lata, May 2000, pps. 579-582
	Maria Esther Martinez Pardo et al., Clinical Application of Amniotic Membranes on a Patient With Epidermolysis Bullosa, 1999, pps. 68-73, Annals of Transplantation, Vol. 4, No. 3-4

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OTHER ART (Including Author, Title, Date, Pertinent Pages, Publisher, Place of Publication, etc.)			
W	Jan Parizek et al., Duraplasty With Pretreated Freeze-Dried Sterilized Human Dura Mater, 1990, pps. 135-143, Sbor. ved. Praci LF UK Hradee Kralove, Vol. 33		
N	Jan Parizek et al., Ovine Pericardium: A New Material For Duraplasty, 1996, pps. 508-513, J. Neurosurg., Vol. 84		
N	Patel et al., Effect of Gamma Radiation and Ethylene Oxide on Papain, 1979, pps. 81-83, Indian. J. Pharm. Sci., Vol. 41, No. 2		
N	L.V. Polezhaeu et al., Repair of Cranial Defects With Regenerating Bone in Grafting Gamma-Irradiated Bone Filings, pps. 57-60		
N	Pollard, The Effect of Ionizing Radiation on Viruses, pps. 65-71		
N	Donald J. Prolo et al., Composite Autogeneic Human Cranioplasty: Frozen Skull Supplemental With Fresh Iliac Corticocancellous Bone, December 1984, pps. 846-851, Neurosurgery, Vol. 15, No. 6		
N	Donald J. Prolo et al., Superior Osteogenesis in Transplanted Allogeneic Canine Skull Following Chemical Sterilization, August 1982, pps. 230-242, Clinical Orthopaedics and Related Research, No. 168		
N	Elena Quaglio et al., Copper Converts the Cellular Prion Protein Into a Protease-resistant Species That Is Distinct From the Scrapie Isoform, April 6, 2001, pps. 11432-11438, The Journal of Biological Chemistry, Vol. 276, No. 14		
N	T.J. Rasmussen et al., The Effects of 4 Mrad of Gamma-Irradiation on the Initial Mechanical Properties of Bone-Patellar Tendon-Bone Grafts, 1994, pps. 188-197, The Journal of Arthroscopic and Related Surgery, Vol. 10, No. 2		
N	Brian D. Reid, The Sterways Process: A New Approach to Inactivating Viruses Using Gamma Radiation, 1998, pps. 125-130, Biologicals, Vol. 26		
N	S.C. Roe et al., The Effect of Gamma Irradiation on a Xenograft Tendon Bioprosthesis, 1992, pps. 149-154, Clinical Materials, Vol. 9		
N	Robert G. Rohwer, Estimation of Scrapie Nucleic Acid MW From Standard Curves for Virus Sensitivity to Ionizing Radiation, March 27, 1986, pp. 381, Nature, Vol. 320, No. 6060		
N	Robert G. Rohwer, Scrapie Infectious Agent is Virus-like in Size and Susceptibility to Inactivation, April 12, 1984, pps. 658-662, Nature, Vol. 308		
N	R.G. Rohwer, The Scrapie Agent: A Virus by Any Other Name, pps. 195-232, Current Topics in Microbiology and Immunology, Vol. 172		
N	Robert G. Rohwer et al., Scrapie-Virus or Viroid, The Case For A Virus, pps. 333-355, Laboratory of Central Nervous System Studies, National Institutes of Neurological and Communicative Disorders and Stroke, National Institutes of Health		
N	Robert G. Rohwer, Virus-Like Sensitivity of the Scrapie Agent to Heat Inactivation, February 10, 1984, pps. 600-602, Science, Vol. 223		
EXAMINER		DATE CONSIDERED	

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

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 August 31, 2001

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 1614

OTHER ART (Including Author, Title, Date, Pertinent Pages, Publisher, Place of Publication, Etc.)

	Robert Sullivan et al., Inactivation of Thirty Viruses by Gamma Radiation, July 1971, pps. 61-65,
	Applied Microbiology, Vol. 22, No. 1
	D. Tylman, Mechanical Character of Liofilized and Sterilized by Gamma-Rays Bone Tissue,
	1996, pps. 229-234, Chirurgia Narzadow Ruchu I, Ortopedia Polska
	W. Welch, A Comparative Study of Different Methods of Processing Aortic Homografts, 1969,
	pps. 746-749, Thorax, Vol. 24
	J.M. White et al., Sterilization of Teeth by Gamma Radiation, September 1994,
	pps. 1560-1567, J. Dent. Res., Vol. 73, No. 9
	Boon-Seng Wong et al., Copper Refolding of Prior Protein, 2000, pps. 1217-1224, Biochemical and
	Biophysical Research Communications, Vol. 276
	Boon-Seng Wong et al., Differential Contribution of Superoxide Dismutase Activity by Prior Protein in
	Vivo, 2000, pps. 136-139, Biochemical and Biophysical Research Communications, Vol. 273
	Boon-Seng Wong et al., Prion Disease: A Loss of Antioxidant Function? 2000, pps. 249-252, Biochemical
	and Biophysical Research Communications, Vol. 275
	D.E. Wyatt et al., Is There Life After Irradiation? Part I: Inactivation of Biological Contaminants, June
	1993, pps. 34-39, BioPharm
	Qi Zhang et al., Ethylene Oxide Does Not Extinguish the Osteoinductive Capacity of Demineralized Bone,
	1997, pps. 104-108, Acta Orthop Scand, Vol. 68, No. 2
	Yongxing Zhang et al., A Comprehensive Study of Physical Parameters, Biomechanical Properties and
	Statistical Correlations of Iliac Crest Bone Wedges Used in Spinal Fusion Surgery, 1994, pps. 304-308,
	Spine, Vol. 19, No. 3
	License Amendment and procedures for Gamma Irradiation of Blood Products, June 22, 1993, pps. 1-18,
	Dept. of Health & Human Services, Food and Drug Administration
	M.F. Alladine et al., $\gamma$ -Radiation Damage to Starr-Edwards Valves, March 16, 1998, pp. 68, The Lancet,
	Letters to the Editor
	Ch. Baquey et al., Radiosterilization of Albuminated Polyester Prostheses, May 1987, pps. 185-189,
	Biomaterials, Vol. 8
	Edward H. Bedrossian, Jr., HIV and Banked Fascia Lata, 1991, pps. 284-288, Ophthalmic Plastic and
	Reconstructive Surgery, Vol. 7, No. 4
	Liu Bingci, Mouse Antibody Response Following Repetitive Injections of Gamma-Irradiated Human
	Placenta Collagen, June 1994, pps. 100-103, Chinese Medical Sciences Journal, Vol. 9, No 2
	A.A. Belov et al., The Influence of $\gamma$ -Radiation on Enzyme Activity of Collalitin in the Process of Storage,
	12/07/89, pps. 519-521, All-Union Research Institute of Textile and Haberdashery Industry, Moscow
	R.G. Burwell, The Fate of Freeze-Dried Bone Allografts, June 1976, pps. 95-111, Transplantation
	Proceedings, Vol VII, No. 2, Supplement 1

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

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GROUP **1614**

(Including Author, Title, Date, Pertinent Pages, Publisher, Place of Publication, Etc.)

N	L. Callegaro et al., Hollow Fiber Immobilized L-Asparaginase: In Vivo and In Vitro Immunologic Studies, 1983, pps. 91-96, The International Journal of Artificial Organs, Vol. 6, No. 2
N	G. Campalani et al., Aortic Valve Replacement With Frozen Irradiated Homografts, 1989, pps. 558-561, Eur. J. Cardio-thoracic Surgery, Vol. 3
N	David T. Cheung et al., The Effect of $\gamma$ -Irradiation on Collagen Molecules, Isolated $\alpha$ -chains, and Crosslinked Native Fibers, 1990, pps. 581-589, Journal of Biomedical Materials Research, Vol. 24
N	David J. Cohen et al., The Fate of Aortic Valve Homografts 12 to 17 Years After Implantation, March 1988, pps. 482-484, Chest, Vol. 93, No. 3
N	A.G. Churchalin et al., Clinical Immunosorbents Basing On Space-Network Polymers, 1998, pps. 1524-1529, All Union Research Institute of Chemical Reagents and Chemicals of Special Purity, Moscow
N	P. De Deyne et al., Some Effects of Gamma Irradiation on Patellar Tendon Allografts, 1991, pps. 51-62, Connective Tissue Research, Vol. 27
N	R.I. Vaida et al., Structural-Functional Peculiarities of Myocardial Capillaries After Resection of the Lungs, 10/21/86, pps. 68-73
N	R. Guidoin et al., A Compound Arterial Prosthesis: The Importance of the Sterilization Procedure on the Healing and Stability of Albuminated Polyester Grafts, March 1985, pps. 122-128, Biomaterials, Vol. 6
N	Ph. Hernigou et al., Radiation Sterilization of Bone and the HIV Virus, 1993, pps. 445-451, Revue de Chirurgie Orthopedique, Vol. 79
N	Hsing-Wen Sung et al., Effects of Various Chemical Sterilization Methods on the Crosslinking and Enzymatic Degradation Characteristics of an Epoxy-Fixed Biological Tissue, December 1996, pps. 376-383, Sterilization of Biological Tissues
N	James R. Malm et al., An Evaluation of Aortic Valve Homografts Sterilized by Electron Beam Energy, October 1967, pps. 471-477, Journal of Thoracic and Cardiovascular Surgery, Vol. 54, No. 4
N	James R. Malm et al., Results of Aortic Valve Replacement Utilizing Irradiated Valve Homografts, pps. 740-747, Annals New York Academy of Sciences
N	W. Oh et al., Mitral Valve Replacement With Preserved Cadaveric Aortic Homografts, May 1973, pps. 712-721, The Journal of Thoracic and Cardiovascular Surgery, Vol. 65, No. 5
N	K. Pietrucha, New Collagen Implant As Dural Substitute, April 1991, pps. 320-323, Biomaterials, Vol. 12
EXAMINER	<i>[Signature]</i>
DATE CONSIDERED	<i>5/8/2003</i>

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

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<b>OTHER ART (Including Author, Title, Date, Pertinent Pages, Publisher, Place of Publication, etc.)</b>			
<i>W</i>	Maria Raptopoulou-Gigi et al., Antimicrobial Proteins in Sterilised Human Milk, January 1, 1977, pps. 12-14, British Medical Journal, Vol. 1		
<i>W</i>	Edward A. Rittenhouse et al., Sterilization of Aortic Valve Grafts for Transplantation, July 1970, pps. 1-5, Aortic Valve Grafts for Transplantation, Archives of Surgery, Vol. 101, No. 1		
<i>W</i>	H. Sato et al., Sterilization of Therapeutic Immunoabsorbents by Ionizing Radiation, 1986, pps. 131-136, The International Journal of Artificial Organs, Vol. 9, No. 2		
<i>W</i>	Richard A. Smith et al., Gamma Irradiation of HIV-1, 2001, pps. 815-819, Journal of Orthopaedic Research, Vol. 19		
<i>W</i>	Barbara Lüssi-Schlatter et al., Die Antimikrobielle Behandlung von Peroralen Enzympräparaten mit Gamma-Strahlen, Pharmazeutisches Institut der Eidgenössischen Technischen Hochschule Zürich Galenische Abteilung		
<i>W</i>	Martindale's Extra Pharmacopoeia, Glucose p. 1265; prior art		
<i>W</i>	The Merck Index, Eleventh Edition Glucose pp. 4353-4354, prior art		
<i>W</i>	G.L. Moore et al., Effects of 4000 Rad. Irradiation on the In Vitro Storage Properties of packed Red Cells, Nov-Dec 1985, pps. 583-585, Final Rept., Pub. In Transfusion, Vol. 25, No 6 (Abstract)		
<i>W</i>	Shcheglova et al., The Effect of the Power of Gamma-Radiation on the Radiation Dose in the Sterilization of Drugs, 1984, pps. 730-732, Khim-Farm Zh, Vol. 18, No. 6 (Abstract)		
<i>W</i>	G.A. Yarygina, Dose Rate Effect on Survival of Microorganisms Used As Test-Cultures in Radiation Sterilization of Medical Products, 1973, pps. 32-39, Radiats. Tekh., No. 9 (Abstract)		
<i>W</i>	O. Cornu et al., Effect of Freeze-Drying and Gamma Irradiation on the Mechanical Properties of Human Cancellous Bone, 2000, pps. 426-431, Journal of Orthopaedic Research, Vol. 18		
<i>W</i>	Anna Dziedzic-Goclawska et al., Effect of Radiation Sterilization on the Osteoinductive Properties and the Rate of Remodeling of Bone Implants Preserved by Lyophilization and Deep-Freezing, November 1991, pps. 30-37, Clinical Orthopaedics and Related Research, Vol. 272		
<i>W</i>	Ole T. Jensen et al., Vertical Guided Bone-Graft Augmentation in a New Canine Mandibular Model, November 3, 1995, pps. 335-343, The International Journal of Oral and Maxillofacial Implants, Vol. 10		
<i>W</i>	Ronald W. Katz et al., Radiation-Sterilized Insoluble Collagenous Bone Matrix is a Functional Carrier of Osteogenin for Bone Induction, 1990, pps. 183-185, Calcified Tissue International, Vol. 47		
<i>W</i>	Everard Munting et al., Effect of Sterilization on Osteoinduction, 1988, pps. 34-38, Acta Orthop Scand, Vol. 59, No. 1		
<i>W</i>	P.A. Puolakkainen et al., The effect of Sterilization on Transforming Growth Factor $\beta$ Isolated From Demineralized Human Bone, 1993, pps. 679-685, Transfusion, Vol. 33, No 8		
<i>W</i>	U. Ripamonti et al., Long-Term Evaluation of Bone Formation by Osteogenic Protein 1 in the Baboon and Relative Efficacy of Bone-Derived Bone Morphogenetic Proteins Delivered by irradiated Xenogeneic Collagenous Matrices, 2000, pps. 1798-1809, Journal of Bone and Mineral Research, Vol. 15, No. 9		
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<i>[Signature]</i>		<i>5/5/2003</i>	

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